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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,500	12/05/2003	Paul A. Levine	A03P1078US01	9708
36802	7590	01/27/2006		
PACESSETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221			EXAMINER JACKSON, BRYAN M	
			ART UNIT 3762	PAPER NUMBER

DATE MAILED: 01/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No.	Applicant(s)	
	10/728,500	LEVINE, PAUL A.	
	Examiner	Art Unit Bryan M. Jackson	3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 05 December 2003.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-12 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-12 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 05 December 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/5/2003</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

The Information disclosure statement (IDS) submitted on 12/05/2003 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Florio (6128533) in view of McClure (6711438).

Florio discloses a ventricular pulse generator and sense channel amplifier (fig 3, 24 and 28), an atrial pulse generator and sense channel amplifier (fig 3, 22 and 26), automatic mode switching (AMS) (title), ventricular refractory period (VREF) (col 8, ln 56-58) and blanking period (col 8, ln 61), an ability to sense R-waves (col 2, ln 3-7), an intrinsic atrial rate where all P-waves including P-waves occurring during the refractory periods are sensed (col 7, ln 40-44), a maximum tracking rate (MTR) which is considered to be a threshold, wherein when the intrinsic atrial rate exceeds the MTR, a control system ignores the P-waves

occurring during the refractory periods and utilizes P-waves outside the refractory period to obtain a sensed functional atrial rate (SFAR) (col 7, ln 12-27), a predetermined upper rate limit referred to as an atrial tachycardia detection rate (ATDR), wherein if a filtered atrial rate (FAR) exceeds the ATDR, a pathological atrial arrhythmia exists (col 4, ln 20-22), a noise response (col 8, ln 49-53 & ln 60-63), a post ventricular atrial blanking (PVAB) period, and a post ventricular atrial refractory period (PVARP).

Florio discloses the claimed invention except for the use of unipolar and combined unipolar/bipolar sensing (claims 1-12). McClure teaches that it is known to use unipolar and bipolar sensing within the atria and ventricles (col 1, ln 50-64) or combipolar sensing (col 2, ln 28-34), and teaches "with combipolar sensing, because the atrial channel is derived based upon voltage differentials between the tips of the two unipolar leads, improved detection of atrial signals is achieved as compared with systems which require the relatively weak atrial electrical signals to be detected based upon voltage differentials generated between the tip of the atrial lead and the body of the device" (col 2, ln 27-34). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pacemaker with automatic PVARP adjustment during automatic mode switching, as taught by Florio, with unipolar, bipolar, or combipolar sensing for the heart, as taught by McClure, in order to provide improved detection of the atrial signals via voltage differentials.

Florio and McClure disclose the claimed invention except for an atrial high rate diagnostic evaluation (claim 2). It would have been obvious to one having

ordinary skill in the art at the time the invention was made to modify the Automatic Mode Switching (AMS) using unipolar and combined unipolar/bipolar sensing modes, as taught by Florio and McClure, with the atrial high rate diagnostic evaluation since it was known in the art that Automatic Mode Switching (AMS) is used to provide mode switching from an atrial tracking to a non-atrial tracking mode upon sensing a high atrial rate, and therefore capable of detecting atrial rate oversensing, such as in atrial tachyarrhythmia episodes.

Florio discloses the claimed invention except for "ignoring events sensed simultaneously on atrial and ventricular channels" for the purpose of determining an atrial rate calculation (claims 3 and 5). McClure teaches that "near-field ventricular signals may be difficult to filter out from atrial signals (col 2, ln 44-56). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pacemaker with automatic PVARP adjustment during automatic mode switching (AMS), as taught by Florio, with ignoring events sensed simultaneously on atrial and ventricular channels when determining an atrial rate since it was known in the art that during a heartbeat, using combipolar sensing, near-field signals within the heart, such as R-waves, cause falsely sensed P-waves.

Florio discloses the claimed invention except for identifying events sensed only on the ventricular channel as being noise and ignoring for the purpose of atrial rate calculation (claim 5). McClure teaches that "significant far-field electrical signals are detected along the intended atrial or ventricular cardiac signals" and that a "far-field signal is a signal originating far from the sensor of

the sensing lead but detected by the sensing lead nonetheless, for example, the atrial cardiac signal derived from the atrial lead will typically include significant ventricular signals" (col 1 & 2, ln 65-67 & 1-6). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify a noise response implemented with a pacemaker with automatic PVARP adjustment during automatic mode switching (AMS), as taught by Florio, with identifying events sensed only on the ventricular channel as noise when determining an atrial rate since it was known in the art that a heartbeat requires an atrial event precedes a ventricular event, and during a heartbeat, far-field signals within the heart, such as P-waves, cause falsely sensed ventricular events.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Florio and McClure (6711438) as applied to claim 7 above, and further in view of McClure (6625490).

Florio and McClure (6711438) disclose the claimed invention except for the ventricular blanking interval and relative refractory period combined being longer than the average R-T interval, and the ventricular blanking interval being shorter than the average R-T interval. McClure (6625490) teaches that it is known to use a post-ventricular atrial refractory period (PVARP) slightly longer than the average R-T duration, wherein the summation of a blanking interval PVAB and a relative refractory window is considered to be equivalent to PVARP (col 22, ln 47-49), and teaches that by measuring the duration of the total R-T segment (R-T duration) of the ventricular signal, the ventricular refractory period

can be set to extend through the end of the T-wave, such that any event is detected as a refractory-sensed event and is not detected as an R-wave allowing for the reliable sensing of R-waves in the ventricular channel and accurate detection of the ventricular rate (col 22, ln 36-44).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the ventricular refractory & blanking period and average R-T interval, as taught by Florio and McClure (6711438), with a post-ventricular atrial refractory period (PVARP) slightly longer than the average R-T duration, wherein the summation of a blanking interval PVAB and a relative refractory window is considered to be equivalent to PVARP, as taught by McClure (6625490), since such a modification would prevent the oversensing of T-waves on the ventricular channel.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the ventricular blanking period and average R-T interval, as taught by Florio and McClure (6711438), with a ventricular blanking period shorter than the average R-T duration, wherein the summation of a blanking interval PVAB and a relative refractory window is considered to be equivalent to PVARP, as taught by McClure (6625490), since such a modification would allow for sensing within the relative refractory period.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. McClure (6650931) discloses a system and method of automatically determining the onsets and ends of cardiac events and far-field

signals. Mann (5788717) discloses atrial rate determination and atrial tachycardia detection in a dual-chamber implantable pacemaker. Betzold (5658320) discloses atrial tachyarrhythmia detection in implantable pulse generators. Sirokman (6047213) discloses an atrial tracking cardiac stimulator.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bryan M. Jackson whose telephone number is 571-272-7335. The examiner can normally be reached on Monday through Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GEORGE R. EVANISKO
PRIMARY EXAMINER

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